Remarks

I. Status of the claims

Claims 1, 4, 7-9, 11, 12, 23, 28-31, and 33 are pending and stand rejected. Claims 1, 7, 9, 11, 23, 28, 30, and 33 have been amended, and claims 2, 3, 5, 6, 10, 13-22, 24-27, and 32 have been canceled.

II. Amendments to the claims

Claims 1, 9, 23, 30 and 33 have been amended to recite that the composition comprises about 1 to 58% by weight of a mixture of hydroxyethylcellulose (HEC) and hydroxypropylmethyl cellulose (HMPC). Applicants note that "[w]ith respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure." M.P.E.P. § 2163.05. Applicants submit that the range about 1 to 58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methyl cellulose or less is inherently supported by the specification. In *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A new claim limitation of "between 35% and 60%" met the description requirement. Similarly, the limitation of about 1 to 58% by weight is supported by the examples. Specifically, example 1 describes a formulation with 58% HEC/HMPC, Example 2 discloses 50% HEC/HMPC and example 3 discloses 55% HEC/HMPC. Thus, the specification as filed provides ample support for the recited range.

The term "pulsatile" has been deleted from the claims.

Claims 1, 9, 23 and 33 have been amended to recite that the recited ingredients, including the pharmaceutically active agent, are provided as a matrix. Support for this amendment can be found, for example, in the specification at page 5, first paragraph and in the examples, which combine these ingredients into a matrix.

Claims 7 and 28 have been amended for clarity by reciting that the composition is film coated with a coating material.

Claim 11 has been amended to depend from claim 9 instead of claim 10, which is now canceled.

No new matter has been added by these amendments.

III. Claim Rejections Under 35 U.S.C. § 112, first paragraph

The Examiner states that the claims do not comply with § 112, first paragraph, as failing to meet the written description requirement. In particular, the Examiner states that the amount of talc of about less than 10% is not supported by the specification. Applicants submit that support for this range can be found on page 3, line 4 of the specification. Additionally, support for less than 10% by weight of magnesium stearate can be found on page 3, line 5 of the specification. Withdrawal of this rejection is requested.

The Examiner also states that the amendment of 15% by weight of HEC and HMPC was not disclosed. This rejection has been obviated by the aforementioned amendment of 15% to 58%. Withdrawal of this rejection is requested.

IV. Rejections under 35 U.S.C. § 103

The Examiner states that all of the components required for controlled release are found in the prior art and that one of ordinary skill "would have been motivated to formulate a controlled release pharmaceutical based on the teachings of the prior art to include all the necessary agents." The Examiner further contends that "much of the relevant literature is very precise in that it either concentrates, for example, on a specific type of polymer . . . ." *Office action* at p. 2. Thus, the Examiner concludes that "one of ordinary skill in the art would be motivated to explore which of the

polymers known in the art would yield a better controlled release delivery of the drug." *Id.* Applicants respectfully traverse.

In order to establish a *prima facie* case of obviousness, the Examiner must determine the scope and content of the prior art, ascertain the differences between the claimed invention and the prior art and resolve the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 (1966). Once the Graham factual inquiries have been resolved, the Examiner must explain why the differences between the cited references and the claims would have been obvious to one of ordinary skill in the art. Fed. Reg. Vol. 72, No. 195, p. 57527. The Supreme Court in *KSR* stressed that "obviousness cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR* 127 S.Ct. 1727, 1740 (2007); see also Fed. Reg. Vol. 72, No. 195, p. 57529. "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." Fed. Reg. Vol. 72, No. 195 at p. 57528.

Weiss in view of Guley taken with Kooichi

The Examiner has rejected claims 1, 4, 7-12, 23 and 28-33 as being allegedly obvious over Weiss in view of U.S. Patent No. 4,309,405 to Guley et al. ("Guley") taken with U.S. Patent No. 4,218,433 to Kooichi et al. ("Kooichi"). The Examiner relies on Weiss for reasons discussed with respect to the withdrawn 102(b) rejection. *Office Action* at p. 5. The Examiner further states with regard to claims 11 and 29 that one skilled in the art would have been motivated to switch aspirin, taught by Weiss, to naproxen since both are non-steroidal antiinflammatory drugs. *Office Action* at p. 5. The Examiner relies on Guley for describing talc and calcium stearate, stating that one skilled in the art would have been motivated to substitute calcium for magnesium stearate, "and expect a

successful result in doing so because both calcium and magnesium are alkaline earth metals." Finally, the Examiner relies on Kooichi for describing a controlled release tablet comprising "methacrylic and methacrylic esters." *Id.* Applicants respectfully traverse.

Weiss fails to disclose 1-58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose provided as a matrix with the other ingredients recited in the instant claims. Weiss merely describes hydroxypropyl methylcellulose in a coating for a compressed tablet, but not hydroxyethyl cellulose.

Additionally, Weiss does not describe that the recited ingredients are provided in a matrix, as claimed. The hydroxypropyl methylcellulose described in Weiss is provided as a coating solution, which is applied to the tablet, and is not a part of the matrix. Carbopol 934, meanwhile, is a part of the Weiss tablet. Thus, these two ingredients cannot be considered to be "provided as a matrix," as recited in the instant claims. As such, the tablets of Weiss lack the sustained release effect achieved with the present claims. *See 1.132 affidavit filed on September 223,* 2004, attached.

Guley and Kooichi fail to remedy the deficiencies of Weiss. Guley describes sustained release pharmaceutical compositions containing at least one drug in both an inner compressed core and an outer sugar layer. *Guley* at col. 1, ll. 11-15. Kooichi describes a constant rate eluting medicinal tablet for use with water soluble pharmaceutical ingredients. *Kooichi* at col. 1, ll. 6-7. Kooichi and Guley, when combined with the teachings of Weiss, fail to provide any rational basis for arriving at the instant claims. Specifically, neither Kooichi or Guley provides any teaching to use 1-58% of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose. Furthermore, nothing in the cited reference combination provides any rational basis for the skilled artisan to combine the presently recited composition ingredients into a matrix, with any reasonable

expectation of success in achieving the sustained delivery applicants have achieved. *See 1.132 Affidavit.* For at least these reasons, Applicants request withdrawal of this rejection.

V. Provisional Non-Statutory Double Patenting

Claims 1, 4, 7-12, 23 and 28-33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent Application No. 11/473,386 ("the '386 application"). Claims 1, 4, 7-12, 23 and 28-33 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 7,090,867. Applicants respectfully request that the Examiner hold in abeyance this obviousness-type double patenting rejection until allowable subject matter is indicated, at which point Applicants will file a terminal disclaimer if necessary.

VI. Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants' attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

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Respectfully submitted,

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